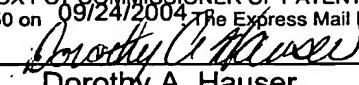


|  |                           |   |  |   |
|--|---------------------------|---|--|---|
| FORM PTO-1390<br>(REV. 01-2003)  |                           | U.S. DEPARTMENT OF COMMERCE PATENT AND TRADEMARK OFFICE |  | ATTORNEY'S DOCKET NUMBER                        |
|  |                           |   |  | 1256-01012                                      |
|  |                           |   |  | U.S. APPLICATION NO. (If known, see 37 CFR 1.5) |
|  |                           |   |  | 10/509065                                       |
| INTERNATIONAL APPLICATION NO.  | INTERNATIONAL FILING DATE | PRIORITY DATE CLAIMED                                   |  |   |
| PCT/US03/07443   | 12 March 2003             | 25 March 2002   |  |   |
| TITLE OF INVENTION   |                           |   |  |   |
| Use of Carbon-2-Modified-19-Nor-Vitamin D Analogs to Induce the Formation of New Bone  |                           |   |  |   |
| APPLICANT(S) FOR DO/EO/US  |                           |   |  |   |
| Hector F. DELUCA; J. Wesley PIKE; Nirupama K. SHEVDE   |                           |   |  |   |
| Applicant herewith submits to the United States Designated/Elected Office (DO/EO/US) the following items and other information:  |                           |   |  |   |
| <p>1. <input checked="" type="checkbox"/> This is a <b>FIRST</b> submission of items concerning a filing under 35 U.S.C. 371.</p> <p>2. <input type="checkbox"/> This is a <b>SECOND</b> or <b>SUBSEQUENT</b> submission of items concerning a filing under 35 U.S.C. 371.</p> <p>3. <input checked="" type="checkbox"/> This is an express request to begin national examination procedures (35 U.S.C. 371(f)). The submission must include items (5), (6), (9) and (21) indicated below.</p> <p>4. <input checked="" type="checkbox"/> The US has been elected (Article 31).</p> <p>5. <input checked="" type="checkbox"/> A copy of the International Application as filed (35 U.S.C. 371(c)(2))</p> <ul style="list-style-type: none"> <li>a. <input checked="" type="checkbox"/> is attached hereto (required only if not communicated by the International Bureau).</li> <li>b. <input type="checkbox"/> has been communicated by the International Bureau.</li> <li>c. <input type="checkbox"/> is not required, as the application was filed in the United States Receiving Office (RO/US).</li> </ul> <p>6. <input type="checkbox"/> An English language translation of the International Application as filed (35 U.S.C. 371(c)(2)).</p> <ul style="list-style-type: none"> <li>a. <input type="checkbox"/> is attached hereto.</li> <li>b. <input type="checkbox"/> has been previously submitted under 35 U.S.C. 154(d)(4).</li> </ul> <p>7. <input checked="" type="checkbox"/> Amendments to the claims of the International Application under PCT Article 19 (35 U.S.C. 371(c)(3))</p> <ul style="list-style-type: none"> <li>a. <input checked="" type="checkbox"/> are attached hereto (required only if not communicated by the International Bureau).</li> <li>b. <input type="checkbox"/> have been communicated by the International Bureau.</li> <li>c. <input type="checkbox"/> have not been made; however, the time limit for making such amendments has NOT expired.</li> <li>d. <input type="checkbox"/> have not been made and will not be made.</li> </ul> <p>8. <input type="checkbox"/> An English language translation of the amendments to the claims under PCT Article 19 (35 U.S.C. 371(c)(3)).</p> <p>9. <input type="checkbox"/> An oath or declaration of the inventor(s) (35 U.S.C. 371(c)(4)).</p> <p>10. <input checked="" type="checkbox"/> An English language translation of the annexes of the International Preliminary Examination Report under PCT Article 36 (35 U.S.C. 371(c)(5)).</p> |                           |   |  |   |
| Items 11 to 20 below concern document(s) or information included:  |                           |   |  |   |
| <p>11. <input type="checkbox"/> An Information Disclosure Statement under 37 CFR 1.97 and 1.98.</p> <p>12. <input type="checkbox"/> An assignment document for recording. A separate cover sheet in compliance with 37 CFR 3.28 and 3.31 is included.</p> <p>13. <input checked="" type="checkbox"/> A preliminary amendment.</p> <p>14. <input type="checkbox"/> An Application Data Sheet under 37 CFR 1.76.</p> <p>15. <input type="checkbox"/> A substitute specification.</p> <p>16. <input type="checkbox"/> A power of attorney and/or change of address letter.</p> <p>17. <input type="checkbox"/> A computer-readable form of the sequence listing in accordance with PCT Rule 13ter.2 and 37 CFR 1.821 - 1.825.</p> <p>18. <input type="checkbox"/> A second copy of the published international application under 35 U.S.C. 154(d)(4).</p> <p>19. <input type="checkbox"/> A second copy of the English language translation of the international application under 35 U.S.C. 154(d)(4).</p> <p>20. <input checked="" type="checkbox"/> Other items or information:</p> <ul style="list-style-type: none"> <li>A. Supplement to Transmittal Letter</li> <li>B. International Preliminary Examination Report</li> </ul>   |                           |   |  |   |

|  |              |  |   |
|--|--------------|--|---|
| U.S. APPLICATION NO. (if known, see 37 CFR 1.5)<br><b>10/509065</b>  |              | INTERNATIONAL APPLICATION NO.<br><b>PCT/US03/07443</b>   | ATTORNEY'S DOCKET NUMBER<br><b>1256-01012</b> |
| <p>21. <input checked="" type="checkbox"/> The following fees are submitted:</p> <p><b>BASIC NATIONAL FEE (37 CFR 1.492 (a) (1) - (5)):</b></p> <p>Neither international preliminary examination fee (37 CFR 1.482) nor international search fee (37 CFR 1.445(a)(2)) paid to USPTO and International Search Report not prepared by the EPO or JPO ..... <b>\$1080.00</b></p> <p>International preliminary examination fee (37 CFR 1.482) not paid to USPTO but International Search Report prepared by the EPO or JPO ..... <b>\$920.00</b></p> <p>International preliminary examination fee (37 CFR 1.482) not paid to USPTO but international search fee (37 CFR 1.445(a)(2)) paid to USPTO ..... <b>\$770.00</b></p> <p>International preliminary examination fee (37 CFR 1.482) paid to USPTO but all claims did not satisfy provisions of PCT Article 33(1)-(4) ..... <b>\$730.00</b></p> <p>International preliminary examination fee (37 CFR 1.482) paid to USPTO and all claims satisfied provisions of PCT Article 33(1)-(4) ..... <b>\$100.00</b></p> |              | <b>CALCULATIONS PTO USE ONLY</b>   |   |
| <b>ENTER APPROPRIATE BASIC FEE AMOUNT =</b>  |              | <b>\$ 920.00</b>   |   |
| Surcharge of <b>\$130.00</b> for furnishing the oath or declaration later than 30 months from the earliest claimed priority date (37 CFR 1.492(e)).  |              | <b>\$ 0.00</b>   |   |
| CLAIMS   | NUMBER FILED | NUMBER EXTRA   | RATE  |
| Total claims   | 28 - 20 =    | 8  | x \$18.00                                     |
| Independent claims   | 1 - 3 =      | 0  | x \$86.00                                     |
| MULTIPLE DEPENDENT CLAIM(S) (if applicable)  |              | + \$290.00   |   |
| <b>TOTAL OF ABOVE CALCULATIONS =</b>   |              | <b>\$ 1,064.00</b>   |   |
| <input type="checkbox"/> Applicant claims small entity status. See 37 CFR 1.27. The fees indicated above are reduced by 1/2.   |              | +  | <b>\$ 0.00</b>                                |
| <b>SUBTOTAL =</b>  |              | <b>\$ 1,064.00</b>   |   |
| Processing fee of <b>\$130.00</b> for furnishing the English translation later than 30 months from the earliest claimed priority date (37 CFR 1.492(f)).   |              | <b>\$ 0.00</b>   |   |
| <b>TOTAL NATIONAL FEE =</b>  |              | <b>\$ 1,064.00</b>   |   |
| Fee for recording the enclosed assignment (37 CFR 1.21(h)). The assignment must be accompanied by an appropriate cover sheet (37 CFR 3.28, 3.31). <b>\$40.00</b> per property  |              | +  | <b>\$ 0.00</b>                                |
| <b>TOTAL FEES ENCLOSED =</b>   |              | <b>\$ 1,064.00</b>   |   |
|  |              | Amount to be refunded:   | \$  |
|  |              | charged:   | \$  |
| <p>a. <input checked="" type="checkbox"/> A check in the amount of <b>\$ 1,064.00</b> to cover the above fees is enclosed.</p> <p>b. <input type="checkbox"/> Please charge my Deposit Account No. _____ in the amount of <b>\$ _____</b> to cover the above fees. A duplicate copy of this sheet is enclosed.</p> <p>c. <input checked="" type="checkbox"/> The Commissioner is hereby authorized to charge any additional fees which may be required, or credit any overpayment to Deposit Account No. <b>012000</b>. A duplicate copy of this sheet is enclosed.</p> <p>d. <input type="checkbox"/> Fees are to be charged to a credit card. <b>WARNING: Information on this form may become public. Credit card information should not be included on this form.</b> Provide credit card information and authorization on PTO-2038.</p>  |              |  |   |
| <p><b>NOTE: Where an appropriate time limit under 37 CFR 1.495 has not been met, a petition to revive (37 CFR 1.137 (a) or (b)) must be filed and granted to restore the application to pending status.</b></p>  |              |  |   |
| SEND ALL CORRESPONDENCE TO:<br>Andrus, Sceales, Starke & Sawall, LLP, 100 East Wisconsin Avenue, Suite 1100, Milwaukee, WI 53202-4178, (414) 271-7590, Facsimile: (414) 271-5770   |              | <br><b>09/24/2004</b><br><b>SIGNATURE</b><br><b>Joseph D. Kuborn</b><br><b>NAME</b><br><b>40,689</b><br><b>REGISTRATION NUMBER</b> |   |
| CERTIFICATE OF EXPRESS MAIL:<br>I hereby certify that this correspondence is being deposited with the United States Postal Service with sufficient postage as EXPRESS MAIL-POST OFFICE TO ADDRESSEE, in an envelope addressed to: BOX PCT COMMISSIONER OF PATENTS, P.O. Box 1450, Alexandria, VA 22313-1450 on <b>09/24/2004</b> . The Express Mail Label is EV477159545US.  |              | <br><b>09/24/2004</b><br><b>Dorothy A. Hauser</b><br><b>Date</b>  |   |

PATENT

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In re the Application of:

Hector F. DeLuca

J. Wesley Pike

Nirupama K. Sheyde

Filed Herein

International Appl. No.

PCT/US03/07443

International Filing Date:

March 12, 2003

Priority Date Claimed:

by Date Claimed:

## USE OF CARBON-2-MODIFIED-19-

## USE OF CARBON-2-MODIFIED- NOR-VITAMIN D ANALOGS TO

## NOR-VITAMIN D ANALOGS TO INDUCE THE FORMATION OF NEW

## INDUCE BONE

) CERTIFICATE OF EXPRESS MAILING  
) I hereby certify that this correspondence is  
) being deposited with the United States  
) Postal Service with sufficient postage as  
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) to: Commissioner for Patents, Alexandria,  
) VA 22313-1450 on this 24th day of  
) September, 2003. The Express Mail Label  
) is EV477159545US.

SUPPLEMENT TO TRANSMITTAL LETTER

Mail Stop: PCT  
Commissioner for Patents  
P.O. Box 1450  
Alexandria, VA 22313-1450

Sir:

This application is being filed to enter the national stage of the PCT pursuant to 37 C.F.R. §1.495(c). The application includes the specification, at least one claim, and the filing fee. The Declaration is not included. The three inventors are as follows:

Hector F. DeLuca  
1809 Highway BB  
Deerfield, WI 53531  
Citizenship: United States

J. Wesley Pike  
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Madison, WI 53717  
Citizenship: United States

Applicant: Hector F. DeLuca et al  
Attorney Docket No.: 1256-01012

Nirupama K. Shevde  
9109 Settler's Road  
Madison, WI 53717  
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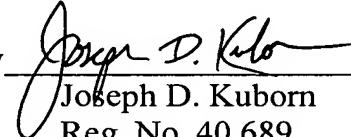
The Declaration will be forwarded promptly upon notification from the U.S. Patent and Trademark Office.

Please address all correspondence and telephone calls regarding this matter to:

Thomas M. Wozny  
ANDRUS, SCEALES, STARKE & SAWALL, LLP  
100 East Wisconsin Avenue, Suite 1100  
Milwaukee, Wisconsin 53202  
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Respectfully submitted,

ANDRUS, SCEALES, STARKE & SAWALL, LLP

By   
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